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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,177	11/23/2001	George A. Cates	1038-1168 MIS:jb	6952

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,177	CATES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on September 12, 2001, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

1. The disclosure is objected to because of the following informalities:

On page 5, line 14, the specification reads as follows:

> Immunity to these antigens, reduces the likelihood of infections and lessens the severity of the disease if infection occurs.

There should not be a comma after the word "antigens."

On page 21, line 4, the specification reads "Mice were bleed one day prior to the first immunization..." The word "bled" is more appropriate for the sentence structure than "bleed."

Appropriate correction is required.

2. The use of the trademark Fluzone® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. In the present case, the applicant has identified the term as a trademark by use of the ® symbol, but has not described the generic composition of the Fluzone vaccine.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising an adjuvant wherein there is an enhanced immune response to the claimed composition when compared to the composition of the adjuvant and RSV component without the influenza component where the adjuvant is PCPP and the influenza preparation is FLUZONE®, does not reasonably provide enablement for a composition comprising any adjuvant or any influenza preparation with such effects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims are rejected for three reasons. First, the applicant is not enabled for the claimed composition wherein the adjuvant can be an adjuvant other than PCPP. Second, the applicant is not enabled for combinations of PCPP with other influenza preparations other than Fluzone®. Third, the applicant has not provided a description of what the influenza preparation in the Fluzone® product comprises such that one practicing the claimed invention would know that the Fluzone® commercially available at such time as it is later being practiced is the same as the one that lead to the synergistic results in the claimed invention.

A claim is commensurate in scope with the enablement when the applicant has provided sufficient disclosure to enable one skilled in the art to practice the claimed invention without undue experimentation. In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988). There must be a "reasonable correlation" between the scope of enablement and the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). This correlation requires that "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." See, In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (CAFC 1991) (explaining why disclosure of one working examples in an unpredictable art was insufficient to enable claims to a generic claim covering bacteria from many different genera). Therefore, although neither working examples, nor an explanation of how the invention work are required, they are factors that may be considered when determining the scope of enablement provided by the applicant.

In the present case, the applicant is claiming a broad genus of compositions that have a certain advantage, the enhancement of the immune effect of the RSV component due to the presence of the adjuvant and influenza virus preparation. This enhancement has a particular feature, wherein the enhanced immune response is due not to the adjuvant alone, but to the combination of the adjuvant and the influenza preparation. In short, the applicant is claiming a form of adjuvant synergy between these two components. Because a synergistic response is by definition an unexpected result, such a limitation imparts unpredictability into the claimed technology. Where the art is unpredictable, enablement of the claimed invention requires more

detail in the description than would be necessary in more predictable fields. See e.g. MPEP § 2164.03; In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970); and In re Vaeck, 20 U.S.P.Q. 2d 1438, 1445 (Fed. Cir. 1991). Thus, in order to enable the identified claims, the applicant would have to provide more guidance than may be needed for claims not requiring the adjuvant synergy.

In the specification, the applicant has provided a single working example. This example shows that PCPP, when combined with the Fluzone® influenza vaccine enhances the immune response to the claimed RSV vaccine compared to the response seen with the RSV alone, or with either the adjuvant or Fluzone® alone. However, the applicant has not provided any guidance as to what other adjuvants would achieve this synergy, either by way of further examples, or by way of explaining what characteristics of the adjuvants lead to this synergy. Therefore, claim 4 is rejected as not enabled because the specification provides no guidance other than the single working example as to what other adjuvants may be used to achieve the same "unexpected result."

The second basis for rejecting the claim, that the applicant is not enabled for combinations of PCPP with influenza preparations other than Fluzone® is for substantially the same reasons as the applicant is not enabled for other adjuvants that PCPP. The applicant is claiming a synergistic limitation, but has not provided any other guidance that the single working example, or a correlation between the full scope of influenza compositions and the claimed synergy. There is no indication that any non-virulent influenza virus preparation would achieve this unexpected result when combined with the PCPP adjuvant and the RSV component of the multivalent vaccine.

Finally, the last enablement rejection is as described above. The applicant has not adequately described the Fluzone® vaccine such that one desiring to practice the claimed invention would know whether or not the Fluzone® available at a later time is the same composition as the one used in the presently claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 19 provides for the use of the immunogenic composition of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

7. Claims 1, 2, 5-18, and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Cates et al. U.S. Patent 6,020,182 (Cates U.S.), in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536. Claim 1 describes immunogenic compositions comprising fusion (F), attachment (G), and matrix (M) proteins of respiratory syncytial virus

(RSV), and an immunoeffective non-virulent influenza virus preparation. The other claims either further identify the claimed composition, or describe a method of using such to immunize a human against diseases caused by these viruses.

The Cates reference teaches an RSV subunit formulation identical to the formulation used as the RSV component of the instantly claimed multivalent vaccine. Cates also teaches that the composition may also comprise an adjuvant, including adjuvants with immunostimulating effects (therefore imparting an enhanced immune response to RSV). Col. 4, lines 6-24. Finally, Cates also teaches the combination of the RSV vaccine with immunogens against other infections, including immunogens against influenza and that the RSV composition may comprise between 1 and 100 μg of the RSV subunit composition. See, e.g. columns 11-16 (showing varying amounts of the RSV from 1 to 100 μg compositions). However, Cates does not teach that the influenza immunogen is a non-virulent influenza virus preparation.

Smith teaches that influenza vaccines licensed at the time the patent was filed comprised inactivated whole (thus non-virulent, and attenuated) or subunit vaccines (comprising influenza antigens)comprising preparations from three viral strains. Webster teaches that the inactivated influenza vaccine should be in amounts of between 1-50 μg, and in safe and effective amounts as determined by conventional methods (thus rendering obvious the 1-100 μg range of the instant claims). Col. 13, lines 16-28. Thus, it would have been obvious to one of ordinary skill in the art to use non-virulent influenza compositions in the composition taught by Cates because such influenza preparations were commonly used in influenza vaccines. Therefore, these references render obvious the claimed composition.

Aside from the suggestion of Cates U.S. to combine the treatments, there are also additional motivations to combine the RSV and influenza preparations. The art of vaccination recognized the value of combining treatment so as to simplify the vaccination process, as well as the recognized goal of combining antigens recommended for routine administration into a single product. See, e.g. Plotkin, p. 508. As both RSV and influenza both require yearly vaccinations due to the antigenic shifts in the viruses, immunogenic compositions against infection by these viruses are prime candidates for such combination. See, Potash, U.S. Patent 5,911,998, cols. 1-2; and Smith, cols. 2-3. Because the Cates teaches that the RSV vaccine may be combined with those other listed immunogens, it would be obvious to one of ordinary skill in the art to combine the RSV vaccine with *any* of those compositions. The statement that the combination may be made is sufficient to render the combination obvious..

8. Claims 1, 2, 5-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al., WO 98/02457 (Cates PCT), published Jan. 22, 1998, in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536.The claims are described above. Cates PCT teaches an RSV subunit formulation identical to the formulation used as the RSV component of the instantly claimed multivalent vaccine. See, claims 2-9, 13, 21, and 23. Cates PCT also teaches that the composition may also comprise an adjuvant. Claim 17. Finally, Cates PCT also teaches the combination of the RSV vaccine with immunogens against other infections, including influenza and that the RSV composition may comprise between 1 and 100 μg of the RSV subunit composition. See e.g., p. 8, and pp. 29 and 31 (Tables 5, 6, and 8, showing varying amounts of the RSV from 1 to 100 μg compositions). However, Cates does not teach that the

influenza immunogen is a non-virulent influenza virus preparation. Such influenza preparations are described in Smith and Webster as applied above. It would have been obvious to one of ordinary skill in the art to combine the Cates PCT reference with the Smith and Webster references for the same reasons as described above with regards Cates U.S.

9. Claims 1, 2, 4, 6-14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S. or Cates PCT as applied to claims 1, 2, 5-18, and 20 above, and further in view of Payne, Vaccine, Vol. 16(1):92-98. Claims 1, 2, 5-18, and 20 were described above. Claim 4 limits the composition to embodiments wherein the adjuvant is PCPP. The teachings of the Cates references were described above. Each of these references teach that the disclosed RSV composition may be used with an adjuvant. Cates U.S., column 4, lines 6-24; Cates PCT, page 7, lines 14-34. Among the adjuvants suggested by these references is polyphosphazene. Id. However, neither of the references teaches that the polyphosphazene is PCPP.

Payne teaches that PCPP is an effective adjuvant for viral vaccines. See e.g. Payne, page 97, right column. Payne also more specifically shows that the adjuvant was effective in the induction of immune responses against influenza virus. Page 95. As the reference teaches that this polyphosphazene is an effective adjuvant for viral vaccines, and as the Cates references teach that polyphospahzenes may be used in the described RSV vaccines, it would have been obvious to one of ordinary skill in the art to use PCPP in the composition described by Cates.

10. Claims 3 and 4 are rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Cates PCT in view of Andrianov, U.S. 5,494,673. In addition to the teachings

of Cates as described above, the reference also lists among the adjuvants that may be used polyphosphazene. Col. 4, line 17. The reference does no teach the use of PCPP specifically, or the additional advantages that would be realized by using this adjuvant.

Andrianov teaches that PCPP is a safe and effective adjuvant, and teaches the use of the adjuvant in influenzae vaccines. It would therefore have been obvious to one of ordinary skill in the art to combine these references to arrive at the claimed composition. Further, although the reference do not teach the enhanced immune response described in claim 3, the advantage described by the claim would have flowed from the combination of the references as described in the art. The fact that the applicant recognized an additional advantage to the suggested modification does not render the claimed invention unobvious. See e.g., MPEP § 2145, paragraph 2, and Ex Parte Obiaya, 227 U.S.P.Q. 58, at 60 (Bd. Pat. App. and Inter. 1985- stating "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious."). Thus, the Cates and Andrianov reference renders the identified claims obvious.

11. Claims 1, 2 5-16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, as applied to claims 1, 3, and 6-18 above, and further in view of Huebner, U.S. Patent 5,612,037. The claims and the Cates U.S. reference are described above. Huebner describes a commercial inactivated influenza vaccine (FLUZONE®) and its administration in a dose of 5μg. See, Huebner, col. 1, lines 15-18; and col. 7, Table III. Because Cates U.S. teaches the combination of the disclosed RSV immunogenic composition with an

influenza immunogen, and as Huebner teaches a known influenza vaccine composition, it would have been obvious to one of ordinary skill in the art to combine the teachings of Cates with Huebner to achieve the claimed composition. The motivation to combine the references and the expectation of success are provided by Cates and the knowledge in the art as described above.

12. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as applied above to claims 1, 3, and 6-18, and further in view Murry et al., Hosp. Pract. 32(7):87-8, 91-4. The claims describe a method of immunizing a human against a disease caused by infection by RSV or influenza by administering the claimed composition wherein the host being treated is a human of at least 18 years of age. The Cates references have been described in part above. The Cates references also seem to indicate that the vaccine described therein is intended for the immunization of children. See, Cates PCT , page 1-3, and Cates U.S., columns 1 and 2 (describing the vaccination of children for RSV). Thus, although the bodies of the references do not appear to exclude the treatment of adults, they do tend to identify children as the primary benefactors of the described vaccine.

However, Murry teaches that RSV infection is a "significant pathogen" in adults as well as in children. Page 87. The reference teaches that the virus may be "as important as influenza in causing morbidity and excess mortality among elderly persons." In view of these teachings suggesting that RSV is a problematic infection in adults, it would have been obvious to one of ordinary skill in the art to have used the vaccine composition suggested by the other references

cited above to vaccinate the elderly (therefore, presumably, at least 18 years of age) against RSV infection.

13. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, in view of Smith and Webster, or in view of Huebner as applied to claims 1, 3, 6-15, and 18 above, and further in view of Potash, U.S. 5,911,998. The claims describe a method of immunizing a human against a disease caused by infection by RSV or influenza by administering the claimed composition wherein the host being treated is a human of at least 18 years of age. The Cates references have been described in part above. The Cates references also seem to indicate that the vaccine described therein is intended for the immunization of children. See, Cates PCT , page 1-3, and Cates U.S., columns 1 and 2 (describing the vaccination of children for RSV). Thus, although the bodies of the references do not appear to exclude the treatment of adults, they do tend to identify children as the primary benefactors of the described vaccine.

Potash, however, teaches that RSV and influenza infections may occur throughout the adult life of a person. Column 1, lines 55-60. Further, the viruses are taught to cause severe respiratory tract disease, and influenza is taught to be a major cause of mortality in the elderly. Id. In view of these teachings, and the teachings of the other references above that indicate the efficacy of the RSV/influenza vaccines disclosed therein, it would have been obvious to one of ordinary skill in the art to use the vaccine composition derived from these references to treat not only children, but to treat adults as well. Thus, it would have been obvious to such a person to se the composition to immunize a person of at least 18 years of age.

14. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as applied above to claims 1, 3, and 6-18, and further in view of Hall et al., J. Infect. Dis., 163:693-698; Crowe, Vaccine, 13:415-421; Groothuis, Journal of Infectious Diseases, 177(2), pp. 467-469 (1998); and Falsey, Vaccine, 14(13), pp. 1214-1218 (1996). Claim 20 describe a method of using the claimed composition to prevent a disease caused by RSV infection in a human wherein the human is at least 18 years old. The Cates, Smith, Webster, and Huebner references are described above.

Groothuis teaches that there are currently no safe and effective RSV vaccines for young infants. P. 467. Crowe teaches that RSV subunit vaccines do not work effectively for all children. Hall teaches that an RSV subunit vaccine is effective in young adults, and suggests that there may eventually be a vaccine available for infants. Falsey teaches that the subunit vaccine was also effective in populations of elderly hosts. Thus, the art indicates that the vaccine is known to be effective in adults, while its efficacy in children, while known in some instances is not generally applicable. It would therefore be obvious to one of ordinary skill in the art to treat a human with the claimed composition, and they would be more motivated to use the composition to treat adults than children due to the inconsistency of the results in regards to children.

15. Claims 1, 2, 4, 6-21 are rejected under 35 U.S.C. 103(a) as being obvious over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739), in view of Smith, Webster,

Payne, and Murry. The claims have been described above, as have the Smith, Webster, Payne, and Murry references.

The identified claims of the copending application describe the invention according to the rejected claims except that they do not teach that the "at least one additional immunogen" required by claim 21 of the copending application is an influenza immunogenic preparation, that the adjuvant required by claim 17 is PCPP, or that the human being vaccinated by the method of claim 20 is at least 18 years of age. However, the reference does teach that one of the immunogenic compositions that may be combined with the claimed RSV composition is an influenza composition. Seeing this, and the teachings of Smith and Webster, the presently claimed composition, with any adjuvant would have been obvious therefrom.

The copending application also identifies polyphosphazene as an adjuvant that may be used in the claimed invention. This teaching, in view of Payne as described above, would have lead to the use of PCPP in the claimed composition and method. Finally, the copending claims indicate that any human may be vaccinated with the claimed composition. This teaching, in view of the teachings of Murry, would have lead one of ordinary skill in the art to use the vaccine to treat elderly humans. Thus, the copending application renders the presently claimed invention obvious.

It is noted that the applied reference shares a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

16. Claims 1, 2, 4, 6-21 are directed to an invention not patentably distinct from claims 1-9, 13, 15-21, 23, and 26 of commonly assigned copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739). Specifically, the identified claims of the copending application describe the invention according to the rejected claims except that they do not teach that the "at least one additional immunogen" required by claim 21 of the copending application is an influenza immunogenic preparation, that the adjuvant required by claim 17 is PCPP, or that the human being vaccinated by the method of claim 20 is at least 18 years of age. However, the reference does teach that one of the immunogenic compositions that may be combined with the claimed RSV composition is an

influenza composition. Seeing this, and the teachings of Smith and Webster, the presently claimed composition, with any adjuvant would have been obvious therefrom.

The copending application also identifies polyphosphazene as an adjuvant that may be used in the claimed invention. This teaching, in view of Payne as described above, would have lead to the use of PCPP in the claimed composition and method. Finally, the copending claims indicate that any human may be vaccinated with the claimed composition. This teaching, in view of the teachings of Murry, would have lead one of ordinary skill in the art to use the vaccine to treat elderly humans. Thus, the copending application renders the presently claimed invention obvious.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 09/950655, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly

assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Double Patenting

17. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. Claims 1-10, 12-16, 20, and 21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1, 2, 4-16, 18, 19, 20, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, and 13 of U.S. Patent No. 6,020,182, in view of Smith et al., U.S. Patent 5,762,939 and Payne. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming vaccine compositions against RSV infections, and the Cates patent teaches that such RSV compositions may be used in combination with other immunogens, including immunogens against influenza. Col. 4, lines 25-34. The application teaches that the embodiments of the non-virulent influenza virus that form a part of the claimed vaccine are known in the art. App.. p. 9. Smith teaches a common influenza immunogenic preparation as described by the claims. Payne teaches that PCPP is an effective adjuvant. As the patent teaches that an adjuvant may be used, it would have been obvious to one of ordinary skill in the art to use PCPP in composition claimed by the '182 patent. It would therefore have been obvious to one of ordinary skill in the art to use the preparation taught by Smith in the composition described by Cates. Therefore, the teachings of the patent render the instantly claimed inventions obvious.

21. Claims 1, and 2, 5-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16 of U.S. Patent No. 6,309,649, in view of Smith et al., U.S. Patent 5,762,939 or Palese et al., U.S. Patent 6022726. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming vaccine compositions against RSV infections. The Cates patent teaches, and claims, that such RSV compositions may be used in combination with other immunogens,

including immunogens against influenza. Col. 4, lines 36-45; claim 13. The application teaches that the embodiments of the non-virulent influenza virus that form a part of the claimed vaccine are known in the art. App.. p. 9. Further, the patent also teaches the use of PCPP as an adjuvant with the RSV composition. Col. 12, lines 5-10. Smith teaches a common influenza immunogenic preparation as described by the claims, and Palese teaches attenuated influenza virus, and that such may be used in vaccines (Claims, and column 2, lines 16-19). It would therefore have been obvious to one of ordinary skill in the art to use the preparation taught by Smith or Palese in the composition described by Cates. Therefore, the teachings of the prior Cates patent in view of the other prior art references render the instantly claimed inventions obvious.

22. Claims 1, 11, 15, and 17-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770, or over these claims in view of Smith or Palese. The claims, and the teachings of Smith and Palese are described above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunogenic composition of claim 11 contains the compositions of claim 12 of the other application. As the copending application is claiming combinations of the claimed RSV vaccine with an influenza immunogenic composition, it would have been obvious to one of ordinary skill in the art to combine the teachings of the other application and Smith or Palese to derive the presently claimed compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1, 2, 4, 6-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739), in view of Smith, Webster, Payne, and Murry. The claims have been described above, as have the Smith, Webster, Payne, and Murry references.

The identified claims of the copending application describe the invention according to the rejected claims except that they do not teach that the "at least one additional immunogen" required by claim 21 of the copending application is an influenza immunogenic preparation, that the adjuvant required by claim 17 is PCPP, or that the human being vaccinated by the method of claim 20 is at least 18 years of age. However, the reference does teach that one of the immunogenic compositions that may be combined with the claimed RSV composition is an influenza composition. Seeing this, and the teachings of Smith and Webster, the presently claimed composition, with any adjuvant would have been obvious therefrom.

The copending application also identifies polyphosphazene as an adjuvant that may be used in the claimed invention. This teaching, in view of Payne as described above, would have lead to the use of PCPP in the claimed composition and method. Finally, the copending claims indicate that any human may be vaccinated with the claimed composition. This teaching, in view of the teachings of Murry, would have lead one of ordinary skill in the art to use the vaccine to treat elderly humans. Thus, the copending application renders the presently claimed invention obvious.

This is a provisional obviousness-type double patenting rejection.

24. The above rejections are, in part, based on the specifications of previously issued patents, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself. Thus, the fact that the patent identified above teaches that the claimed RSV vaccine composition may be combined with an influenza composition may be used to reject the current claims even though the patent claims do not suggest such a combination.

Conclusion

25. No claims are allowed.

26. The following prior art reference is made of record and is considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Volvovitz, WP 96/33738. This reference teaches inactivated influenza virus vaccines. The reference is not used in the above rejections as it is redundant to the Smith and Webster references.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
March 20, 2003

JAMES HOUSEL 3/23/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600